510(k) Summary

Applicant:

DEC 20 2013

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Date of preparation of 510(k) summary:

December 19, 2013

A. 510(k) Number:

K133503

B. Purpose for Submission:

To obtain substantial equivalence for the AmpliVue® GBS Assay

C. Measurand:

Thiolase (atoB) gene of *S. agalactiae* (Group B Streptococcus)

D. Type of Test:

Helicase-dependent amplification (HDA)

E. Applicant:

Quidel Corporation

510(k) Summary

F. Proprietary and Established Names:

AmpliVue® GBS Assay

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NJR - Nucleic Acid Amplification Assay System, Group B Streptococcus, Direct Specimen	Class I (Non-exempt)	21 CFR 866.3740 – *Streptococcus spp.* Serological Reagents	Microbiology (83)

H. Intended Use:

1. Intended Use(s):

The AmpliVue® GBS Assay is a qualitative *in vitro* diagnostic test for the rapid detection of Group B Streptococcus from vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation in an LIM enrichment broth culture. The AmpliVue® GBS Assay utilizes helicase-dependent amplification (HDA) of the thiolase (atoB) gene sequence and a self-contained disposable amplification detection device that allows for manual evaluation of assay results. Results can be used as an aid in determining the colonization status of antepartum women.

The AmpliVue® GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

The AmpliVue® GBS Assay is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

2. Indication(s) for Use:

The AmpliVue® GBS Assay is a qualitative *in vitro* diagnostic test for the rapid detection of Group B Streptococcus from vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation in an LIM enrichment broth culture. The AmpliVue® GBS Assay utilizes helicase-dependent amplification (HDA) of the thiolase (atoB) gene sequence and a self-contained disposable amplification detection device that allows for manual evaluation of assay results. Results can be used as an aid in determining the colonization status of antepartum women.

The AmpliVue® GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

The AmpliVue® GBS Assay is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

3. Special conditions for use statement(s):

   - For in vitro diagnostic use only
   - For prescription use only

4. Special instrument requirements:

   None

I. Device Description:

The AmpliVue® GBS Assay combines simple sample processing, an isothermal amplification technology named helicase-dependent amplification (HDA), and a self-contained disposable amplicon detection device, for the detection of Group B Streptococcus from vaginal /rectal swabs following 18 to 24 hours incubation in Lim enrichment broth culture.

A small amount of cultured specimen is transferred into a dilution tube. The diluted sample culture is then transferred into a lysis tube, and the cells are lysed by simple heat treatment. After heat treatment, an aliquot of the lysed sample is added to a reaction tube containing a lyophilized mix of HDA reagents including primers specific for the amplification of the thiolase (atoB) gene. The rationale behind the selection of this particular target sequence were: 1) a BLAST search of this gene resulted in no thiolase with significant homology in species other than those belonging to *S. agalactiae*; 2) the gene is conserved in GBS based on the recent GBS Genome project. The assay also includes a process control that monitors sample processing, confirms the integrity of the assay reagents and cassette detection, and assays for HDA-inhibitors that may be present within a broth culture. After completion of the HDA reaction, the reaction tube is transferred to a cassette for rapid detection with test result displayed as test and/or control lines in the window of the cassette.

Materials Provided:

- 16 Tests per Kit

Symbol	Component	Quantity	Storage
❶	Detection Cassettes	16/kit	2° to 30°C
❷	Dilution Buffer	16 tubes/kit 0.35 mL	2° to 8°C
❸	Lysis Buffer	16 tubes/kit 0.35 mL	2° to 8°C
❹	Reaction Tubes	16 tubes/kit	2° to 8°C
❺	Amplicon Cartridge	16/kit	2° to 30°C

Materials required but not provided:

- External controls for Group B Streptococcus (e.g. AmpliVue® GBS Control Set, which contains positive and negative controls, serves as an external processing and extraction control)
- Sterile DNAse-free filter-blocked or positive displacement micropipettor tips
- Micropipettor
- Stopwatch or timer
- Scissors or a blade
- Micro tube tray
- Heat block capable of 95° C ± 2° C temperature
- Heat block with heated lid capable of 64° ± 2° C temperature
- Thermometer

J. Substantial Equivalence Information:

1. Predicate device name(s):

   illumigene® GBS Assay, external control kit (Meridian Bioscience, Inc.)

2. Predicate 510(k) number(s):

   K112125

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3. Comparison with predicate:

Similarities		
Item	**Device (K133503)**	**Predicate (K112125)**
Intended Use	Qualitative *in vitro* diagnostic test for the rapid detection of Group B *Streptococcus* from vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation in enriched Lim broth culture	Same
Sample Types	Enriched Lim broth cultures of Vaginal/Rectal swab specimens	Same
Sample Heat Lysis	Manual	Same
Self-Contained System Assay after sample preparation	Yes	Same

Differences		
Item	**Device (K133503)**	**Predicate (K112125)**
Sample Type Enrichment Culture	Lim broth cultures, only	TransVag and Lim broth
DNA Amplification Technology	Helicase-dependent amplification (HDA)	Loop-mediated isothermal **DNA** amplification (LAMP)
Target Sequence Detected	Thiolase (atoB) gene	213 base pair (bp) sequence residing in the 593-805 bp region of *S. agalactiae* genome Segment 3
Detection Technique	Manual	Automated
Instrument	None	illumipro-10
Testing Time	75 - 90 minutes	60 minutes
Clinical Sensitivity	99.5% (95% CI: 96.9-100%)	97.4% (95% CI: 91.9 - 99.0%)

Differences		
Item	**Device (K133503)**	**Predicate (K112125)**
Clinical Specificity	92.7% (95% CI: 90.5-94.3%)	92.3% (95% CI: 90.0 - 94.1%)

K. Standard/Guidance Document Referenced (if applicable):

Not applicable

L. Test Principle:

Following a specimen lysis step, amplification of the atoB gene occurs if GBS is present in the HDA reaction. Competitive amplification of the process control DNA also takes place unless amplification inhibitory substances are present or the sample processing fails. The HDA reaction is asymmetric so that an excess of single stranded DNA is formed from a biotinylated primer present within the reaction mix.

The capture probes for each amplicon bind to the corresponding biotinylated single-stranded DNA and this dual-labeled probe-amplicon hybrid are then detected by using a proprietary detection cassette. The bottom line captures the FITC-labeled probe-target amplicon and the top line captures the DNP-labeled probe-control amplicon. The biotin label attracts the streptavidin-conjugated color particles for visualization and the test result is shown as colored lines visible to the naked eye. The self-contained cassette is comprised of two individual components: an amplicon cartridge that holds the running buffer and a single 0.2-mL thin wall reaction tube containing the amplified product; and the detection chamber which houses the amplicon Quidel Corporation cartridge and a vertical-flow DNA detection strip embedded into the cassette. The DNA detection strip is coated with an anti-FITC antibody and an anti-DNP antibody that serve as the GBS test (T) line and the control (C) line respectively in the assay. A razor blade and a plastic pin located at the bottom of the detection chamber open the HDA reaction tube and the running buffer bulb when the handle of the detection chamber is closed. The mixture flows through a fiberglass paper connected to the DNA detection strip that is attached with a fiberglass pad pre-loaded with streptavidin-conjugated color particles for color visualization. Detection of GBS is reported when the T line is visible through the detection window of the cassette. No detection of GBS is reported when only the C line is displayed. The assay is regarded as unresolved when neither line is displayed.

M. Performance Characteristics:

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Reproducibility

   In order to confirm the reproducibility of the AmpliVue® GBS Assay, a blinded and randomized study panel containing *Streptococcus agalactiae* negative and positive samples were tested at three test sites (one in-house laboratory and two clinical sites). Each site tested a reproducibility panel and Assay Controls for five days in triplicate. Testing was done by two operators at each site. Each operator ran the panel once a day using one lot of AmpliVue® GBS Assay. A total of 540 specimens were tested (including controls). The AmpliVue® GBS Assay generated the following reproducible results in this study.

	Site #1		Site #2		Site #3				
Category	**#expected results/# tested**	**% Agree-ment**	**#expected results/# tested**	**% Agree-ment**	**#expected results/# tested**	**% Agree-ment**	**Overall Results**		**95% Confidence Interval**
GBS High Negative	18/30	60%	24/30	80%	28/30	93%	70/90	78%	68% - 85%
GBS Low Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%	95% - 100%
GBS Moderate Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%	95% - 100%
GBS Negative	30/30	100%	30/30	100%	30/30	100%	90/90	100%	95% - 100%
GBS Positive Control	30/30	100%	30/30	100%	30/30	100%	90/90	100%	95% - 100%
GBS Negative Control	30/30	100%	30/30	100%	30/30	100%	90/90	100%	95% - 100%

The results suggest that there are no significant differences between different users, different sites and different lots in different days. Reproducibility studies are acceptable.

b. Linearity/assay reportable range:

Not applicable – This assay is qualitative.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:

Not applicable. This assay is qualitative.

Specimen Stability:

A study was performed to determine the stability of samples in Lim Broth that are used in the AmpliVue® GBS Assay. A freshly grown stock of GBS bacteria of known titer was used to spike a pooled negative clinical sample in Lim Broth. The spiked samples were stored at 4°C or 25°C and tested at 2h, 8h, 24h and 25h time points prior to being tested in the AmpliVue® GBS Assay.

Based on this study, clinical samples are expected to be stable at both 25°C and 4°C for up to 25 hours.

Controls:

Controls (AmpliVue® GBS Control Set, which contains positive and negative controls, serves as an external processing and extraction control) were run on the AmpliVue® GBS Assay each day of testing. These controls are described as follows:

a. The *process control* is used to monitor sample processing, to detect HDA inhibitory specimens and to confirm the integrity of assay reagents and cassette detection. The process control is included in the Dilution Buffer tube.

b. The *external positive control* may be treated as a patient specimen. The control should be sampled and tested as if it were a broth culture and processed as described in the Assay Procedure. The external positive control is intended to monitor substantial reagent and cassette failure.

c. The *external negative control* may be treated as a patient specimen. The control should be sampled and tested as if it were a broth culture and processed as described in the Assay Procedure. The external negative control is used to detect reagent or environmental contamination (or carry-over) by GBS DNA or amplicon.

d. Detection limit:

The analytical sensitivity (limit of detection or LoD) of the AmpliVue® GBS Assay was determined using quantified (CFU/mL) cultures of six *Streptococcus agalactiae* strains serially diluted in a Lim broth. The LoD is defined as the lowest concentration at which 95% of all replicates tested positive.

The GBS bacterial strains were freshly grown. The cell density of these bacterial suspensions was estimated using the McFarland standard OD reading. After a cell suspension of 0.25 McFarland units were established, the bacteria were serially diluted in Lim broth to densities ranging from 3x to 0.3x LoD levels based on preliminary studies.

Each test dilution was run as 20 replicates in the AmpliVue® assay and plated on 20 TSA + 5% blood plates. The study was performed in 5 experiments of 14 assays per strain. For each experiment, 4 replicates of each of the three Lim broth bacterial dilutions were performed, along with a positive and a negative run control. All five experiments of the LoD study for each strain were completed within 8 hours. The stocks of cells were stored on ice or at 4 °C when not in use.

The highest dilution where at least 19 of 20 replicates show detection of GBS (95% positivity) was assigned the Limit of Detection of the strain. The CFU/mL was calculated based on the average bacterial plate count of the dilution.

The LoD for the six strains tested ranged from 1.24×10^5 to 1.39×10^6 CFU/mL. Based on this data the reported LoD for the AmpliVue® GBS Assay is the highest value of the six strains: 1.39×10^6 CFU/mL.

LoD Results

Strain	CFU/mL
BAA-611	1.39×10^6
SS617	6.96×10^5
SS618	6.02×10^5
SS619	5.64×10^5
ATCC 12403	8.84×10^5
SS700	1.24×10^5

e. *Analytical specificity:*

Cross Reactivity:

A study was conducted using two strains of *Streptococcus agalactiae* (BAA-611 and SS617) tested near LoD to evaluate the AmpliVue® GBS Assay for potential interference using a panel of 91 organisms (76 bacteria, three yeast, 11 viruses and a parasite listed in the tables below) potentially found in vaginal/rectal samples cross-react with the AmpliVue® GBS Assay. Human genomic DNA was also evaluated for cross-reactivity. The microorganisms were tested above clinically relevant levels (bacteria $\geq 1 \times 10^6$ CFU/mL, viruses $\geq 1 \times 10^5$ $TCID_{50}$/mL).

Bacteria		
Abiotrophia defective	*Enterobacter cloacae*	*Salmonella choleraesius (typhimurium)*
Acinetobacter baumanii	*Enterococcus faecalis*	*Salmonella enterica arizonae*
Aeromonas hydrophila	*Enterococcus faecium*	*Salmonella enterica enterica Serovar Typhimurium*
Alcaligenes faecalis faecalis	*Escherischia coli*	*Salmonella enterica indica*
Bacillus cereus	*Escherischia fergusonii*	*Serratia liquefaciens*
Bacillus subtilis	*Gardnerella vaginalis*	*Serratia marcescens*
Bacteroides fragilis	*Helicobacter pylori*	*Shigella boydii*
Bifidobacterium adolescentis	*Klebsiella oxytoca*	*Shigella flexneri*
Campylobacter fetus	*Klebsiella pneumoniae*	*Shigella sonnei*
Campylobacter hyointestinalis	*Lactobacillus acidophilus*	*Staphyloccocus aureus*
Campylobacter jejuni	*Legionella pneumophila*	*Staphylococcus epidermidis*
Chlamydia trachomatis	*Listeria monocytogenes*	*Stenotrophomonas maltophila*
Citrobacter freundii	*Mobiluncus mulieris*	*Streptoccocus mutans*
Clostridium bifermentans	*Moraxella cartarrhalis*	*Streptoccocus pyogenes*
Clostridium butyricum	*Morganella morganii*	*Streptococcus bovis*

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Bacteria		
Clostridium difficile	*Neisseria gonorrhoeae*	*Streptococcus dysgalactiae*
Clostridium haemolyticum	*Peptostreptococcus anaerobius*	*Streptococcus gordonii*
Clostridium novyi	*Pleisiomonas shigelloides*	*Streptococcus intermedius*
Clostridium orbiscindens	*Porphyromonas asaccharolytica*	*Streptococcus mitis*
Clostridium perfringens	*Prevotella melaninogenica*	*Streptococcus oralis*
Clostridium septicum	*Proteus mirabilus*	*Streptococcus pneumonia*
Clostridium sordellii	*Providencia alcalifaciens*	*Streptococcus salivarius*
Clostridium sporogenes	*Pseudomonas aeruginosa*	*Streptococcus suis*
Edwardsiella tarda	*Pseudomonas fluorescens*	*Streptococcus uberis*
Enterobacter aerogenes	*S. dysgalactiae equisimilis*	*Vibrio parahaemolyticus*
		Yersinia enterocolitica

Yeast		
Candida albicans	*Candida glabrata*	*Candida parapsilosis*

Viruses		
Adenovirus	Enterovirus	Norovirus
CMV	HPV-16	Rotavirus
Coxsackie virus	HSV1 (Macintyre)	VZV
Echovirus	HSV2 (G)	

Parasite
Trichomonas vaginalis

None of the organisms or viruses tested above cross-reacts with the performance of the AmpliVue® GBS Assay. In addition, human genomic DNA does not interfere with the performance of the AmpliVue® GBS Assay.

Interference:

A study was conducted using two strains of *Streptococcus agalactiae* (BAA-611 and SS617) tested near LoD to evaluate the AmpliVue® GBS Assay for potential interference using a panel consisting of 34 substances (listed in the table below) found in vaginal/rectal specimens. Substances were introduced into the assay dilution tubes at concentrations which were medically relevant. Each of the strains was tested for each substance. None of the substances tested were found to interfere with the AmpliVue® GBS Assay.

Substance Name	**Concentration Tested**	**GBS Result**	**Substance Name**	**Concentration Tested**	**GBS Result**
ImodiumAD® (Loperamide HCl)	1.5 µg/mL	Positive	Witch Hazel	0.15%	Positive
Mucin	4.5 µg/mL	Positive	Benzalkonium Cl	0.00018%	Positive
Barium sulfate	7.5 µg/mL	Positive	Fecal Sugar - Dextrose	1.5 µg/mL	Positive
Fecal Fat - Palmitic Acid	1.95 µg/mL	Positive	Human Serum Albumin	15 µg/mL	Positive
Mylanta®Mg(OH)2	0.15 µg/mL	Positive	Mineral Oil	0.015% v/v	Positive
Hemorrhoidal cream (Phenylephrine HCl)	30 µg/mL	Positive	Triclosan	0.001%	Positive
Hemoglobin	4.8 µg/mL	Positive	Hemorrhoidal cream (Target Brand Cream)	0.015% of swab	Positive
Mylanta® Al(OH)3	0.15 µg/mL	Positive	Anusol® (Hydrocortisone Cream)	0.015% of swab	Positive
Prilosec® (Esomeprazole Magnesium Hydrate)	0.75 µg/mL	Positive	Desitin® (Zinc Oxide)	0.015% of swab	Positive
Tums® (Calcium Carbonate)	0.75 µg/mL	Positive	KY Jelly	0.015% of swab	Positive

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Substance Name	Concentration Tested	GBS Result	Substance Name	Concentration Tested	GBS Result
Fecal Fat - Stearic Acid	39 µg/mL	Positive	Petroleum Jelly	0.015% of swab	Positive
Kaopectate® (Bismuth Subsalicylate)	1.3 µg/mL	Positive	Condom Swab (Nonoxynol-9)	0.015% of swab	Positive
Tagamet® (Cimetidine)	0.75 µg/mL	Positive	Body Powder	0.015% of swab	Positive
Ethanol	0.015% v/v	Positive	Meconium	0.015% of swab	Positive
Miconazole Nitrate Salt	0.003%	Positive	Amniotic Fluid	0.0750%	Positive
Nystatin	15 USP U/mL	Positive	Stool	0.015%	Positive
Urine	0.05%	Positive	Whole Blood	0.006%	Positive

Analytical Reactivity (Inclusivity):

The reactivity of the AmpliVue® GBS Assay was evaluated against an additional twelve strains of *Streptococcus agalactiae*. The testing was performed near the level of detection for the assay (1x LoD).

Each strain was tested as three replicates in the AmpliVue® GBS Assay. The study was performed in multiple experiments of no more than 14 assays per experiment. For each experiment, three replicates of up to four strains were performed, along with a positive and a negative run control. All twelve strains were detected by the AmpliVue® GBS Assay in this study at a LoD of 1084 CFU/assay (1.39×10^6 CFU/mL).

Inclusivity Results		
Bacterial Strain	**Serotype**	**Vendor**
ATCC 12973	II	ATCC
CCUG 28551	IV	CCUG
CCUG 29785	VI	CCUG
ATCC 49449	X	ATCC
ATCC 27956	not typed	ATCC
ATCC 7077	not typed	ATCC
ATCC 4768	not typed	ATCC
ATCC 12927	not typed	ATCC
ATCC 9925	not typed	ATCC

Inclusivity Results		
Bacterial Strain	**Serotype**	**Vendor**
ATCC 55194	not typed	ATCC
ATCC 55191	not typed	ATCC
CNCTC 6609	VII	CNCTC

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Performance characteristics of the AmpliVue® GBS Assay were established during a prospective study conducted from July to November 2013. Nine hundred eleven specimens used for this study were collected from antepartum women between 35 to 37 weeks' gestation at four distinct geographical sites across the United States. The age range for these women was between 15 to 44 years old.

Nine hundred eleven specimens were tested by both the AmpliVue® GBS Assay and bacterial culture. Three specimens (0.3%) were invalid in the AmpliVue® GBS Assay when initially tested. Three specimens remained invalid upon repeat testing. We elected to calculate clinical performance based on the initial test result obtained for each specimen. Therefore, the data below is for the remaining nine hundred eight specimens.

Combined Sites								
		Bacterial Culture					**95% CI**	
AmpliVue® GBS Assay		**POS**	**NEG**	**Total**	**Sensitivity**	99.5%	96.9%	100%
	POS	196	52*	248	**Specificity**	92.7%	90.5%	94.3%
	NEG	1**	659	660				
	Total	197	711	908				

* Fifty-two (52) discordant specimens (AmpliVue Positive/Bacterial Culture Negative) reported above were tested with an FDA-cleared molecular device for the detection of GBS. Thirty-nine (39) of these specimens were positive for GBS, and thirteen (13) were negative.

** The one (1) discordant specimen (AmpliVue Negative/Bacterial Culture Positive) reported above was tested with an FDA-cleared molecular device for the detection of GBS, and was negative.

b. Clinical specificity:

See Section 3a.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values:

Clinical performance of the AmpliVue® GBS assay with Lim enrichment broth was established in specimens from antepartum women at four clinical sites during a clinical study performed in 2013. Nine hundred and eight specimens collected from antepartum women between 35 to 37 weeks' gestation at four distinct geographical sites across the United States, were tested. The age range for these women was between 15 to 44 years old. The percentage of positive cases as determined by the AmpliVue ® GBS assay during the study was 27.3% (248 of 908).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

QUIDEL CORPORATION
RONALD H. LOLLAR
SENIOR DIRECTOR CLINICAL AND QUALITY AFFAIRS
2005 EAST STATE ST., SUITE 100
ATHENS OH 45701

December 20, 2013

Re: K133503
Trade/Device Name: AmpliVue® GBS Assay
Regulation Number: 21 CFR 866.3740
Regulation Name: *Streptococcus spp.* serological reagents
Regulatory Class: I
Product Code: NJR
Dated: November 13, 2013
Received: November 14, 2013

Dear Mr. Lollar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133503

Device Name: AmpliVue® GBS Assay

Indications For Use:

The AmpliVue® GBS Assay is a qualitative in vitro diagnostic test for the rapid detection of Group B Streptococcus from vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation in an LIM enrichment broth culture. The AmpliVue® GBS Assay utilizes helicase-dependent amplification (HDA) of the Thiolase (atoB) gene sequence and a self-contained disposable amplification detection device that allows for manual evaluation of assay results. Results can be used as an aid in determining the colonization status of antepartum women.

The AmpliVue® GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

The AmpliVue® GBS Assay is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Ribhi Shawar -S
2013.12.17 13:52:50 -05'00'